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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Appellants: Tamisha Clark)
Barry H. Chilton)
Serial No.: 10/783,910) Group Art Unit:
Filed: February 20, 2004) 1774
For: MEDICAL DEVICE WITH)
ADHERENT COATING,)
AND METHOD FOR)
PREPARING SAME) Examiner: Jill M. Gray
GRAFT)
Docket No.: 3010-1091)

BRIEF FOR CLARK AND CHILTON

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants appeal from the final rejection dated May 20, 2007 of claims 1-8, 10-12, 14-16, 22-24 and 26 of this application. This appeal applies to each of these claims.

Real Party in Interest

Wilson-Cook Medical Inc. is the Real Party in Interest.

Related Appeals and Interferences

There are no related appeals or interferences.

Status of Claims

Claims cancelled: 9, 13, 17-21, 25 and 27-30

Claims pending: 1-8, 10-12, 14-16, 22-24 and 26

Claims on appeal: 1-8, 10-12, 14-16, 22-24 and 26

Status of Amendments

No amendments were presented subsequent to the final office action forming the basis for appeal.

Summary of the Claimed Subject Matter

In the field of medical devices such as wire guides and catheters, it is often desired to coat the device with another substance such as a material to increase the lubricity of the surface or to serve as a carrier for release of a therapeutic substance. Achieving good adherence of these coatings to the underlying medical device is a problem. This is particularly so when the surface of the medical device upon which the coating is to be placed is made with a material, such as a fluoropolymer, which is chosen

specifically for its inert, non-reactive, non-adherent qualities. A number of different coating strategies had been suggested in the prior art; however, at the time the present invention was made, needs still remained. In presently claimed aspects of the present invention, the applicants discovered a solution to this problem. The applicants discovered that by using metallic sodium or another like powerful chemical etchant, chemical alterations could be made to the stable, non-reactive fluoropolymer surface which enabled the application and adherence of lubricious or therapeutic coatings to the altered fluoropolymer surface. The type of etched surface provided by a metallic sodium etchant is called as a "carbonaceous surface". In its powerful attack of the fluoropolymer, the metallic sodium etchant creates significant imperfections in the fluoropolymer by removing fluorine atoms. The resulting radicals form oxygen-containing organic groups at positions at which the fluorine atoms have been removed, sufficiently to increase the hydrophilicity of the fluoropolymer surface to obtain adherence of the lubricious or therapeutic coating. Accordingly, the pending claims of the application are directed to medical devices, for example wire guides, which include a member having a fluoropolymer coating, surface or portion. Further, the fluoropolymer has "an etched carbonaceous surface, said etched carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer" have been removed. The medical devices further include a lubricious and/or therapeutic coating on the carbonaceous surface. Thus, the present claimed invention has solved the problem of adhering coatings to fluoropolymer surfaces by

providing a specialized etched carbonaceous surface, the structure of which is distinctly defined in the claims.

Issues on Appeal

Whether claims 1-8, 10-12, 14-16, 22-24 and 26 are unpatentable under 35 U.S.C. §102(b) as anticipated by or, in the alternative under 35 U.S.C. § 103(a) as obvious over Palermo, U.S. Patent No. 6,139,510.

Grouping of Claims

For purposes of this appeal:

Claims 1-8, 10-12, 14-16, 22-24 and 26 stand and fall together.

Argument

A. Summary of the Argument

Four independent claims and their associated dependent claims are pending in this appeal: independent claim 1 and claims 2-7 dependent thereon; independent claim 8 and claims 10-11 dependent thereon; independent claim 12 and claims 14-16 dependent thereon; and independent claim 22 and claims 23-24 and 26 dependent thereon. Each of

the independent claims is directed to a medical device including a modified fluoropolymer coating, portion or surface, and a lubricious and/or therapeutic coating on the modified surface. Specifically as to the modified fluoropolymer:

Independent claim 1 requires:

a fluoropolymer coating including an etched carbonaceous surface, said etched carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer coating have been removed;

Independent claim 8 requires:

a fluoropolymer portion having an etched carbonaceous surface, said etched carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer portion have been removed;

Independent claim 12 requires:

an etched fluoropolymer portion having a carbonaceous surface, said carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer portion have been removed; and

Independent claim 22 requires:

said fluoropolymer surface having been treated to remove fluorine atoms and form oxygen-containing organic groups to increase the hydrophilic character of the fluoropolymer surface.

The Examiner has asserted that the Palermo reference renders these claims unpatentable because it anticipates them or renders them obvious. However, the Examiner has not made out a *prima facie* case for either rejection, and thus the rejections are erroneous.

On anticipation, the Examiner argues that the Palermo reference inherently arrives at the claimed invention because it describes an “etched hydrocarbonaceous surface”. The Examiner’s stated basis for concluding that inherency exists is:

Regarding the limitation that the etched surface includes oxygen-containing organic groups formed at position [sic] at which fluorine atoms have been removed, it is the examiner’s position that the etched hydrocarbonaceous surfaces [of Palermo] are substantially similar to those contemplated by applicants. Accordingly, in the absence of factual evidence to the contrary, the examiner has reason to believe that etched carbonaceous surfaces of the prior art includes [sic] oxygen-containing organic groups formed at positions at which fluorine atoms have been removed.

Office Action dated March 20, 2007, p. 2, bottom paragraph. This stated basis is circular and amounts only to a statement that “the Examiner believes” that the prior art structure has all of the features of the claimed structure. No explicit fact finding or articulated technical reasoning is set forth whatsoever. Conclusory statements as to an Examiner’s belief are not sufficient to support a rejection for inherent anticipation. At a minimum, such a rejection requires an explanation including sound technical reasoning why the

claimed features *necessarily* occur in the reference. That has not been provided. No *prima facie* case of anticipation has been made.

Moreover, in the above passage, the Examiner states that the Palermo reference teaches “etched carbonaceous surfaces”. No such teaching is present in Palermo, which only describes “hydrocarbonaceous residues” in an entirely different context, without mention of etching thereof. Again, no *prima facie* case of anticipation has been made.

On obviousness, the Examiner has not set out any basis for the rejection. The Examiner does state in passing a belief that “the etched carbonaceous surfaces are substantially similar to those contemplated by applicants” (see passage quoted above). However, (1) this is not applied with any context in an obviousness rejection; and (2) “substantially similar” is not a proper basis for a conclusion of obviousness. To support a proper rejection for obviousness, explicit fact finding and reasoning as to why it would be obvious to a person of ordinary skill in the art to modify the Palermo reference to arrive at the invention would be needed. No such explanation has been provided. No *prima facie* case of obviousness has been made.

Further, Palermo *could not* be used to make out a proper case for anticipation or obviousness of the claims. As fully discussed in the detailed arguments below, Palermo expressly teaches the preparation of unmodified fluoropolymer surfaces, rather than modified fluoropolymers as claimed. In doing so, Palermo teaches directly away from the invention rather than to it.

In summary, no *prima facie* case for either rejection based on Palermo has been made, and none could be. The dependent claims incorporate all limitations of their

respective independent claims and similarly enjoy the distinctions noted above. The rejections are in error as to all claims and should be reversed.

B. An Overview of Pertinent Patent Law

(i) Anticipation

A prior art reference does not anticipate a patent claim unless the reference discloses all of the limitations of the claims. *Kallman v. Kimberly-Clark Corp.*, 713 F2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983). A limitation cannot be found to be inherent in a reference unless that limitation *necessarily* occurs in the reference. As the Court stated in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981): “Inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”

(ii) Obviousness

When rejecting claims under 35 U.S.C. § 103, “the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art.” *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992).¹ To establish a *prima facie* case of obviousness, the Examiner must provide objective evidence 1) of some suggestion or

¹ Citing *In re Piasecki and Meyers*, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984).

motivation to combine or modify one or more prior art references,² 2) that the suggested combination or modification has a reasonable expectation of success,³ and 3) that the prior art reference or references, when combined, suggest or teach all of applicant's claim limitations. MPEP § 2143. As held by the Federal Circuit, "[t]hese findings or evidence must be specific, clear, and particular." *In re Lee*, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir. 2002). Moreover, in finding that the test for obviousness should not be applied too inflexibly, the Supreme Court nonetheless held that factual findings made by the Examiner and articulated reasoning are necessary underpinnings to establish obviousness and must be made explicit. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). A mere conclusory statement cannot support the legal conclusion of obviousness. *KSR Int'l Co.*, 127 S. Ct. at 1741. Rather, the Examiner must identify how a person of ordinary skill in the art would, by known methods, combine the elements in the way the claimed invention does. *Id.*

C. Detailed Arguments

1. Claims 1-8, 10-12, 14-16, 22-24 and 26 are not anticipated under 35 U.S.C. §102(b) by Palermo (U.S. 6,139,510)

The issue here is whether the Palermo reference anticipates claims 1-8, 10-12, 14-16, 22-24 and 26. Anticipation requires that each and every element of the claim be

² This motivation must be found in the references or within the body of knowledge available to a person of ordinary skill in the art at the time applicant's invention was conceived. See, MPEP § 2142.

taught, expressly or inherently, by a single reference. A limitation cannot be found to be inherent in a reference unless that limitation *necessarily* occurs in the reference.

Probabilities or possibilities are not enough. Certainty is required.

The independent claims from the rejected group are 1, 8, 12, and 22. Each is directed to a medical device, and each requires a specific modified fluoropolymer structure, and a lubricious and/or therapeutic coating on the modified fluoropolymer structure. Specifically as to the modified fluoropolymer:

Independent claim 1 requires:

a fluoropolymer coating including an etched carbonaceous surface, said etched carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer coating have been removed;

Independent claim 8 requires:

a fluoropolymer portion having an etched carbonaceous surface, said etched carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer portion have been removed;

Independent claim 12 requires:

an etched fluoropolymer portion having a carbonaceous surface, said carbonaceous surface including oxygen-containing organic groups formed

³ “Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure.” In re Vaeck, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991) (citing In re

at positions at which fluorine atoms of said fluoropolymer portion have been removed; and

Independent claim 22 requires:

said fluoropolymer surface having been treated to remove fluorine atoms and form oxygen-containing organic groups to increase the hydrophilic character of the fluoropolymer surface.

In support of the anticipation rejection, the Examiner has stated that “Palermo teaches a medical guidewire comprising an elongate wire, an etched hydrocarbonaceous surface, wherein the hydrocarbon can be a fluoropolymer and a lubricious coating adhered thereto.” Office Action dated June 26, 2006, p. 2, bottom paragraph. Later, the Examiner added the statement:

Regarding the limitation that the etched surface includes oxygen-containing organic groups formed at position *[sic]* at which fluorine atoms have been removed, it is the examiner’s position that the etched hydrocarbonaceous surfaces [of Palermo] are substantially similar to those contemplated by applicants. Accordingly, in the absence of factual evidence to the contrary, the examiner has reason to believe that etched carbonaceous surfaces of the prior art includes *[sic]* oxygen-containing organic groups formed at positions at which fluorine atoms have been removed.

Dow Chemical Co., 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988)).

Office Action dated March 20, 2007, p. 2, bottom paragraph. This stated basis is circular and amounts only to a statement that “the Examiner believes” that the prior art structure has all of the features of the claimed structure. No technical reasoning is set forth as to why this is the Examiner’s belief. Conclusory statements as to an Examiner’s belief are not sufficient to support a rejection for inherent anticipation. At a minimum, such a rejection requires an articulated explanation including sound technical reasoning why the claimed feature *necessarily* occurs in the reference. That has not been provided, and thus no *prima facie* case of anticipation has been made.

Moreover, in the above passages, the Examiner states that the Palermo reference teaches the preparation of “etched hydrocarbonaceous surface” (2006 Action) and “etched carbonaceous surfaces” (2007 Action). Palermo contains no such teachings. Rather, Palermo refers to “hydrocarbonaceous residues” in its Examples (see e.g. Col. 14, line 13). As taught by Palermo, this refers to a first, plasma-polymerized layer (tie layer) on the guidewire core, upon which second upper layer (e.g. a lubricious layer) is coated. See Col. 12, line 60 to Col. 13, line 12. While this first layer is the layer that the Examiner asserts is an “etched” layer, no etching of this layer is described at all. The Palermo teaching is to form *the expected, parent polymer* from the reaction of the monomers described at the top of Col. 13, *not* some modified form thereof as specifically set forth in the instant claims. In fact, this is the express teaching of Palermo at Col. 12, lines 27-34, where it states that the material of the tie layer “must be able to tolerate the various other solvents, cleaners, sterilization procedures, etc. to which the guidewire and its components are placed during other production steps”. Palermo does not teach

forming a modified structure from the deposited parent polymer. Palermo teaches preserving the parent structure! This is the antithesis of anticipation of the present claims.

Further, Palermo does not teach the formed oxygen-containing organic groups in the fluoropolymer, as claimed, which facilitate bonding of the lubricous and/or therapeutic coating. Nowhere are such groups mentioned and in fact, Palermo theorizes quite to the contrary -- that C-C bonds are provided in the tie layer for subsequent covalent bonding to the outer hydrophilic coating. Col. 13, lines 12-14. How then can it be properly reasoned that the claimed oxygen-containing organic groups *necessarily* occur in the Palermo fluoropolymer? It cannot.

In summary, no *prima facie* case for anticipation of the independent claims by Palermo has been made, and none could be made. The reference itself teaches avoidance of the limitations of the independent claims. The dependent claims include all limitations of their respective independent claims and thus the above reasoning applies to them as well. The rejection for anticipation is in error as to all claims and should be reversed.

2. *Claims 1-8, 10-12, 14-16, 22-24 and 26 are Nonobvious Under 35 U.S.C. §103(a) Over Palmero (U.S. 6,139,510)*

The obviousness rejection was introduced for the first time in the latest Office Action, dated March 20, 2007. However, in doing so, the Examiner did not set forth any basis for the obviousness rejection. In the midst of a longer passage, the Examiner does assert that “the etched carbonaceous surfaces are substantially similar to those

contemplated by applicants” (see passage quoted above). However, as a first point of reply, this statement was not made with any context in an obviousness rejection, and thus it is unclear how to interpret the statement. Further, if such a statement were made in an attempt to support an obviousness rejection, it would clearly be insufficient. A bare conclusion that something is “substantially similar” to that which is claimed is not a proper basis for a finding of obviousness. As noted above, factual findings by the Examiner and articulated reasoning are necessary underpinnings to establish obviousness and must be made explicit, and mere conclusory statements cannot support the legal conclusion of obviousness. No such explicit factual findings and articulated reasoning have been provided. No *prima facie* case of obviousness has been made.

Further, it has long been held that teachings away in references are strong determinants against finding obviousness. Palermo teaches forming *the expected, parent polymer* from the reaction of the monomers described at the top of Col. 13, *not* some modified form thereof as specifically set forth in the instant claims. This is the express teaching and desire of Palermo at Col. 12, lines 27-34, where it states that the material of the tie layer “must be able to tolerate the various other solvents, cleaners, sterilization procedures, etc. to which the guidewire and its components are placed during other production steps”. Accordingly, Palermo does not teach forming a modified structure from the deposited parent polymer, but rather expressly teaches preserving the parent structure. Still further, Palermo does not teach the formed oxygen-containing organic groups in the fluoropolymer, as claimed, which facilitate bonding of the lubricous and/or therapeutic coating. Such groups are certainly not mentioned and in fact, Palermo

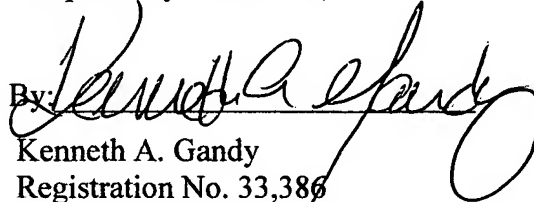
theorizes quite to the contrary -- that C-C bonds are provided in the tie layer for subsequent covalent bonding to the outer hydrophilic coating. Col. 13, lines 12-14. Thus, Palermo is not only silent as to these claimed features, but teaches directly against them. This buttresses the conclusion that the claims are not obvious over Palermo.

In summary, no *prima facie* case for obviousness over Palermo has been made as to the independent claims, and none could be made. The reference itself teaches away from the limitations of the independent claims. The dependent claims incorporate all limitations of their respective independent claims and similarly enjoy the distinctions noted above. The rejection for obviousness is in error as to all claims and should be reversed.

Conclusion

For the above reasons, the Examiner's rejections of claims 1-8, 10-12, 14-16, 22-24 and 26 under 35 U.S.C. §§102(b) and/or 103(a) are in error. Applicants respectfully request reversal of the present rejections and passage of the application to issuance.

Respectfully Submitted,

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Appendix

Copy of Claims on Appeal

WHAT IS CLAIMED IS:

1. (Previously Amended) A medical wire guide, comprising:

an elongate wire;

a fluoropolymer coating on said elongate wire, said fluoropolymer coating including an etched carbonaceous surface, said etched carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer coating have been removed; and

a lubricious and/or therapeutic coating adhered to said etched carbonaceous surface.
2. (Previously Presented) The medical wire guide of claim 1, wherein the fluoropolymer is polytetrafluoroethylene.
3. (Previously Presented) The medical wire guide of claim 1, which is an exchange wire guide.
4. (Previously Presented) The medical wire guide of claim 1, including at least one system of indicia thereon.

5. (Previously Presented) The medical wire guide of claim 1, having a lubricious coating adhered to said etched carbonaceous surface.

6. (Previously Presented) The medical wire guide of claim 5, wherein said lubricious coating comprises one or more polymers non-covalently adhered to the carbonaceous surface.

7. (Previously Presented) The medical wire guide of claim 5, wherein said lubricious coating comprises polyvinylpyrrolidone or a copolymer thereof.

8. (Previously Amended) A medical device, comprising:
an elongate member for traversing a bodily passage;
the elongate member including a fluoropolymer portion having an etched carbonaceous surface, said etched carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer portion have been removed; and

a lubricious and/or therapeutic coating on said surface.

9. (Cancelled)

10. (Previously Amended) The medical device of claim 8, wherein the fluoropolymer is polytetrafluoroethylene.

11. (Previously Presented) The medical device of claim 8, which is a catheter or wire guide.

12. (Previously Amended) A medical device, comprising:
a member for traversing or implantation within a bodily passage;
the member having an etched fluoropolymer portion having a carbonaceous surface, said carbonaceous surface including oxygen-containing organic groups formed at positions at which fluorine atoms of said fluoropolymer portion have been removed; and
a lubricious and/or therapeutic coating adhered to said carbonaceous surface.

13. (Cancelled)

14. (Previously Presented) The medical device of claim 12, which is a wire guide, catheter, or stent.

15. (Previously Presented) The medical device of claim 12, wherein a lubricious coating is adhered to said carbonaceous surface.

16. (Previously Presented) The medical device of claim 12, wherein a therapeutic coating is adhered to said carbonaceous surface, the therapeutic coating containing an antibiotic or anti-thrombogenic agent.

17–21. (Cancelled)

22. (Previously Amended) A medical wire guide, comprising:
an elongate member having a fluoropolymer surface;
said fluoropolymer surface having been treated to remove fluorine atoms and form oxygen-containing organic groups to increase the hydrophilic character of the fluoropolymer surface; and
a lubricious and/or therapeutic coating adhered to the treated fluoropolymer surface.

23. (Previously Presented) The medical wire guide of claim 22, which has a lubricious coating adhered to the treated fluoropolymer surface.

24. (Previously Presented) The medical wire guide of claim 23, wherein the lubricious coating also includes a therapeutic agent.

25. (Cancelled)

26. (Previously Presented) The medical wire guide of claim 25, wherein the fluoropolymer is polytetrafluoroethylene.

27-30. (Cancelled)